ABSTRACT

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Title of diploma thesis: Forced degradation studies of dimethindene maleate using HPLC

The aims of this thesis were to perform forced degradation of dimethindene maleate and to optimize the chromatographic conditions for the determination of dimethindene maleate and its related compounds.

The stress testing was conducted with drug product/drug in order to exam its stability. Decomposition of the product can lead to loss of the content of the active substance, loss of their pharmacological activity or forming of degradation products.

Dimethindene maleate is an antihistamine drug. He affects H_1 histamine receptors.

Nowadays, high performance liquid chromatography (HPLC) is one of the most used separation techniques for the determination of the drug stability.

The stability of dimethindene maleate was investigated using stress testing (forced degradation studies). Dimethindene was stable in aqueous and acid solution as well as under heating (70°C). Significant degradation was observed when the drug was subjected to basic and oxidation stress conditions; this led to the formation of two degradation products DP_1 and DP_2 (described using retention times).

A Zorbax SB CN column (150 × 4.6 mm, 5 µm) was used to perform the optimal analyses. The mobile phase was composed of acetonitrile and 0.02 M ammonium phosphate buffer pH 6.5 (pH adjusted with phosphoric acid and triethylamine) 50:50 (v/v) and the flow-rate was 1.0 ml min^{-1}. The detection was performed at 258 nm. Butylparaben was used as an internal standard.

The proposed stability-indicating method was validated and it is suitable for the quality control laboratory and for the simultaneous determination of dimethindene and its related compounds.